ARTIFICIAL VERTEBRAL DISK REPLACEMENT IMPLANT WITH CROSSBAR SPACER AND METHOD

INVENTORS:

STEVE MITCHELL

CERTIFICATE OF MAILING BY "EXPRESS MAIL"
UNDER 37 C.F.R. §1.10

"Express Mail" mailing label number: EV 326482365 US
Date of Mailing: 10/14/03

I hereby certify that this correspondence is being deposited with the United States Postal Service, utilizing the "Express Mail Post Office to Addressee" service addressed to: **MAIL STOP PATENT APPLICATION, COMMISSIONER FOR PATENTS, P.O. BOX 1450, ALEXANDRIA, VIRGINIA 22313-1450** and mailed on the above Date of Mailing with the above "Express Mail" mailing label number.

Tina M. Galdos (Signature)
Name: Tina M. Galdos
Signature Date: 10/14/03

ARTIFICIAL VERTEBRAL DISK REPLACEMENT IMPLANT WITH CROSSBAR SPACER AND METHOD

INVENTOR:

STEVE MITCHELL

CLAIM OF PRIORITY

[0001] This application claims priority to U.S. Provisional Application No. 60/422,021, filed on October 29, 2002, entitled "ARTIFICIAL VERTEBRAL DISK REPLACEMENT IMPLANT WITH CROSSBAR SPACER AND METHOD" (Attorney Docket No. KLYC-01065US1), which is included herein by reference.

CROSS-REFERENCE TO RELATED APPLICATIONS

[0002] This application is related to U.S. Provisional Application No. 60/422,039, filed October 29, 2002, entitled "ARTIFICIAL VERTEBRAL DISK REPLACEMENT IMPLANT WITH TRANSLATING PIVOT POINT AND METHOD," (Attorney Docket No. KLYCD-05007US0), U.S. Patent Application No. 10/___,___, filed October 14, 2003, entitled "ARTIFICIAL VERTEBRAL DISK REPLACEMENT IMPLANT WITH TRANSLATING PIVOT POINT AND METHOD" (Attorney Docket No. KLYCD-05007US1), U.S. Provisional Application No. 60/422,011, filed October 29, 2002, entitled "TOOLS FOR IMPLANTING AN ARTIFICIAL VERTEBRAL DISK AND METHOD" (Attorney Docket No. KLYCD-05009US0), U.S. Patent Application No. 10/___,___, filed October 14, 2003, entitled "TOOLS FOR IMPLANTING AN ARTIFICIAL VERTEBRAL DISK AND METHOD" (Attorney Docket No. KLYCD-05009US1), U.S. Provisional Application No. 60/422,022, filed October 29,

2002, entitled "ARTIFICIAL VERTEBRAL DISK REPLACEMENT IMPLANT WITH A SPACER AND METHOD," (Attorney Docket No. KLYCD-05010US0), and U.S. Patent Application No. 10/___,___, filed October 14, 2003, entitled "ARTIFICIAL VERTEBRAL DISK REPLACEMENT IMPLANT WITH SPACER AND METHOD," (Attorney Docket No. KLYCD-05010US1), which are incorporated herein by reference.

FIELD OF THE INVENTION

[0003] This invention relates to an artificial vertebral disk replacement and method.

BACKGROUND OF THE INVENTION

[0004] The spinal column is a biomechanical structure composed primarily of ligaments, muscles, vertebrae and intervertebral disks. The biomechanical functions of the spine include: (1) support of the body, which involves the transfer of the weight and the bending movements of the head, trunk and arms to the pelvis and legs, (2) complex physiological motion between these parts, and (3) protection of the spinal cord and nerve roots.

[0005] As the present society ages, it is anticipated that there will be an increase in adverse spinal conditions which are characteristic of older people. Pain associated with such conditions can be relieved by medication and/or surgery. Of course, it is desirable to eliminate the need for major surgery for all individuals, and, in particular, for the elderly.

[0006] More particularly, over the years, a variety of intervertebral implants have been developed in an effort to relieve the pain associated with degenerative and dysfunctional disk conditions. For example, U.S. Patent 4,349,921 to Kuntz discloses an intervertebral disk prosthesis. The Kuntz prosthesis is designed to restore the space between the disks.

[0007] U.S. Patent 4,714,469 to Kenna discloses a spinal implant that fuses vertebrae to the implant. The implant has a rigid body that fits between the vertebra with a protuberance extending from a vertebral contacting surface and extends into the vertebral body.

[0008] U.S. Patent 5,258,031 to Salib et al. discloses another prosthetic disk with a ball that fits into a socket.

[0009] U.S. Patents 5,425,773 and 5,562,738 are related patents to Boyd et al. that disclose a disk arthroplasty device for replacement of the spinal disk. A ball-and-socket are provided to enable rotation.

[0010] U.S. Patent 5,534,029 to Shima discloses an articulated vertebral body spacer with a pair of upper and lower joint pieces inserted between the vertebra. An intermediate layer is provided to allow for movement between the upper joint piece and the lower joint piece.

[0011] U.S. Patent 5,782,832 to Larsen et al. discloses a two-piece ball-and-socket spinal implant with upper and lower plates for insertion within the intervertebral space.

[0012] U.S. Patent 6,156,067 to Bryan et al. discloses a prosthesis having two plates with a nucleus therebetween.

[0013] None of these solutions provide an implant that restores a wide range of natural movement.

[0014] Accordingly, there needs to be developed implants for alleviating such conditions and restoring natural movement.

SUMMARY OF THE INVENTION

[0015] Embodiments of the present invention are directed to providing an implant for alleviating discomfort associated with the spinal column. One embodiment of the implant is characterized by having a first plate and a second plate with a crossbar therebetween.

[0016] Other aspects, objects, features and elements of embodiments of the invention are described or are evident from the accompanying specification, claims and figures.

BRIEF DESCRIPTION OF THE DRAWINGS

[0017] **FIG. 1A** is a front view of an embodiment of an implant of the invention. **FIG. 1B** is a side view of an embodiment of an implant of the invention. **FIG. 1C** is a top view of an embodiment of the implant of the invention. **FIG. 1D** is a top view of an embodiment of the first surface of the top plate of the implant of the invention. **FIG. 1E** is a perspective view of an embodiment of the upper plate of the implant of the invention. **FIG. 1F** is a plan view of the first surface of the lower plate of an embodiment of the implant of the invention. **FIG. 1G** is a perspective view of the lower plate of an embodiment of the implant of the invention. **FIG. 1H** is a cross-sectional view of the upper and lower plates of an embodiment of the implant of the invention taken at H-H in **FIG. 1A**.

[0018] **FIG. 2A** is an upper view of a crossbar of an embodiment of the implant of the invention. **FIG. 2B** is a side view of a crossbar of an embodiment of the implant of the invention. **FIG. 2C** is a lower view of a crossbar of an embodiment of the implant of the invention. **FIG. 2D** is a perspective view of a crossbar of an embodiment of the implant of the invention.

[0019] **FIG. 3** is a perspective view of an assembled implant of an embodiment the invention.

[0020] **FIG. 4** is a side view of the implant implanted between the vertebral bodies.

[0021] **FIG. 5** is a block diagram showing the method steps for implanting the implant of the invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS OF THE INVENTION

[0022] The following description is presented to enable any person skilled in the art to make and use the invention. Various modifications to the embodiments described will be readily apparent to those skilled in the art, and the principles defined herein can be applied to other embodiments and applications without departing from the spirit and scope of the present invention as defined by the appended claims. Thus, the present invention is not intended to be limited to the embodiments shown, but is to be accorded the widest scope consistent with the principles and features disclosed herein. To the extent necessary to achieve a complete understanding of the invention disclosed, the specification and drawings of all patents and patent applications cited in this application are incorporated herein by reference.

[0023] **FIG. 1A** shows an embodiment of the implant ***100*** of the invention. The implant ***100*** has a first part or plate ***110*** that is configured to mate with a first vertebra and a second part or plate ***120*** that is configured to mate with a second vertebra. The first plate ***110*** is an upper plate and the second plate ***120*** is a lower plate. A third part ***130*** that sits between the first plate ***110*** and the second plate ***120*** is also provided. The third part ***130*** acts as a spacer between the first plate ***110*** and the second plate ***120*** and facilitates pivotal or rotational and also twisting movement of the first plate ***110*** and the second plate ***120***, relative to each other. The third part ***130*** is in the form of a crossbar as discussed in more detail below.

[0024] The upper plate ***110*** has a first surface ***112*** from which a keel ***114*** extends with teeth ***115***. The teeth in this embodiment point forward or anteriorly when the embodiment is meant to be put into a slot in a vertebral body from the anterior of the spine. The teeth in an alternative embodiment would point rearward or posteriorly when the embodiment is meant to be put into a slot in a vertebral body from the posterior of the spine. The first surface ***112***, or upper surface, abuts the vertebral body when the implant ***100*** is implanted. The first keel ***114*** extends into the vertebral body to anchor the

implant into position. The second surface ***116***, or lower surface, engages the spacer ***130*** of the implant and faces the second plate ***120***. The second surface ***116*** can form a planar surface that is parallel to the first surface ***112***, or can form a planar surface that is not parallel to the first surface ***112***.

[0025] When the implant is implanted between spinous processes the planar surfaces corresponding to the first surface ***112*** and the second surface ***116*** of the first plate ***110*** lie within, or substantially within, the axial plane of the body, while the first keel ***114*** (which is at or near a 90° angle from the surfaces ***112, 116***) is aligned within the sagittal plane of the body.

[0026] The lower plate ***120*** has a first surface ***122*** from which a keel ***124*** extends with teeth ***125***. The first surface ***122***, or lower surface, abuts the vertebral body when the implant ***100*** is implanted. The second keel ***124*** extends into the vertebral body to anchor the implant into position. The second surface ***126***, or upper surface, engages the spacer ***130*** of the implant and faces the first plate ***110***. The second surface ***126*** can form a planar surface that is parallel to the first surface ***122***, or can form a planar surface that is not parallel to the first surface. The first surface ***112*** of the first plate ***110*** can be parallel to the first surface ***122*** of the second plate ***120*** when the implant ***100*** is assembled and is in a neutral position (i.e., the position where the first plate ***110*** has not rotated relative to the second plate ***120***). Alternatively, the first surface ***112*** of the first plate ***110*** can be non-parallel to the planar surface of the first surface ***122*** of the second plate ***120*** when the implant ***100*** is assembled and in a neutral position.

[0027] As with the first plate, when the implant is implanted between vertebral bodies the planar surfaces corresponding to the first surface ***122*** and the second surface ***126*** of the second plate ***120*** lie within, or substantially within, the axial plane of the body while the second keel ***124*** (which is at or near a 90° angle from the surfaces ***122, 126***) is aligned within the sagittal plane of the body.

[0028] **FIG. 1B** shows a side view of an embodiment of the implant ***100*** of the invention shown in **FIG. 1A**. Again, the implant ***100*** has a first plate ***110*** that is configured to mate with a first vertebra and a second plate ***120*** that is configured to mate with a second vertebra. The spacer ***130*** separates the first plate ***110*** from the second plate ***120***. **FIG. 1C** shows a top view of the upper plate ***110*** with the upper surface ***112*** and the upper keel ***114.*** As evidenced from the upper view, the perimeter shape of the upper plate ***110*** can be configured to correspond to the perimeter shape of a vertebral disk. This is particularly advantageous where a single implant is placed between two vertebral bodies from an anterior approach. As will be appreciated by those of skill in the art, the perimeter shape of the upper plate ***110*** and the lower plate ***120*** can be the same.

[0029] **FIG. 1D** and **FIG. 1E** show an embodiment of the first or upper plate ***110*** of the implant ***100*** of the invention. The upper plate ***110*** has a second surface ***116*** having a channel ***150*** therein. As will be discussed below, the spacer includes a beam which can be placed into the channel ***150*** in order to allow the first and second plates of the assembled implant to pivot or rotate relative to each other. The curved side ***152*** of the first plate ***110*** is oriented to be anterior ***A*** after the device is implanted. The flat side ***154*** of the first plate ***110*** is oriented to be posterior ***P*** after the device is implanted. As shown in **FIG. 1E**, the second surface ***116*** can be formed so that it is received with a ridge ***117*** surrounding the second surface ***116***.

[0030] **FIG. 1F** and **FIG. 1G** show the second or lower plate ***120*** of the implant ***100*** of the invention. The lower plate ***120*** has a second surface ***126*** having a channel ***160*** therein. As will be discussed below, the spacer includes a beam which can be placed into the channel ***160*** in order to allow the first and second plates of the assembled implant to pivot or rotate relative to each other. The curved side ***162*** of the second plate ***120*** is oriented to be anterior ***A*** after the device is implanted. The flat side ***164*** of the second plate ***120*** is oriented to be posterior ***P*** after the device is implanted. As shown

in **FIG. 1G**, the second surface ***126*** can be formed so that it is recessed with a ridge ***127*** surrounding the second surface ***126***.

[0031] **FIG. 1H** is a cross-section of the upper plate ***110*** and the lower plate ***120*** taken along the lines H-H of **FIG. 1A**. As shown in **FIG. 1H**, the second surface ***116*** of the first plate ***110*** faces the second surface ***126*** of the second plate ***120***.

[0032] In **FIG. 2**, the crossbar or spacer ***130*** is shown. **FIG. 2A** is an upper view of an embodiment of a crossbar or spacer ***130*** of the implant of the invention. The crossbar ***130*** has a first beam ***210*** and a second beam ***220***. Each beam ***210, 220,*** has a first end ***212, 222,*** and a second end ***214, 224,*** and a midpoint ***216, 226***, respectively. **FIG. 2B** shows a side view of a crossbar ***130*** of the implant ***100*** of the invention. As is apparent from the side view, the first beam ***210*** can be configured to sit above the second beam ***220***. **FIG. 2C** shows the crossbar ***130*** of the implant of the invention from a bottom view with the first beam ***210*** configured to sit above the second beam ***220***.

[0033] The first beam ***210*** can be configured to be positioned transversely along the length of the second beam ***220*** at a point preferably corresponding about the midpoint ***226*** of the second beam ***220***. The second beam ***220*** can be configured to be positioned along the length of the first beam ***210*** at a point preferably corresponding about the midpoint ***216*** of the first beam ***210***. Where both beams are positioned at the respective midpoints ***216, 226*** the crossbar forms a "+".

[0034] In the alternative embodiment, the first beam ***210*** can also be configured to be positioned transversely along the length of the second beam ***220*** at a point corresponding to a location between the midpoint ***226*** and an end (***222, 224***). The second beam ***220*** can be configured to be positioned transversely along the length of the first beam ***210*** at a point corresponding to about the midpoint ***216*** of the first beam 210. Where one beam ***210, 220*** is positioned along the length between the midpoint and an end of the other beam, the crossbar forms "T".

[0035] In constructing the crossbar ***130***, the first beam ***210*** can be formed integrally with the second beam ***220*** such that is unitary in construction. Alternatively, the first beam ***210*** can be adhered to the second beam ***220*** using a suitable method, such as spot welding.

[0036] **FIG. 2D** shows a perspective view of a crossbar or spacer ***130*** of the implant of the invention. As shown in **FIG. 2D**, the first beam ***210*** and the second beam ***220*** are configured so that the second beam ***220*** is positioned along the length of the first beam ***210*** at a point between the midpoint ***226*** of the second beam ***220*** and an end ***222*** of the second beam ***220***.

[0037] Viewing **FIGS. 1A, 1B** and **3**, an assembled embodiment of the implant ***100*** of the invention is depicted. The implant ***100*** has a first plate ***110*** that is configured to mate with a first vertebra and a second plate ***120*** that is configured to mate with a second vertebra. A crossbar ***130*** that sits between the first plate ***110*** and the second plate ***120*** is also provided. As is evident from the figures, the upper beam ***210*** is placed in the channel ***150*** of the upper plate ***110*** such that the upper beam is about perpendicular to the keels ***114*** and ***124***. As can be seen from **FIG. 1B**, the upper beam is positioned toward the posterior of the implant ***100***. In alternative embodiments the upper beam can be positioned midway between the posterior and the anterior of the implant ***100***. The lower beam ***220*** is placed in the channel ***160*** of the lower plate ***120*** such that the lower beam is about parallel to the keels ***114*** and ***124***. The crossbar ***130*** acts as a spacer between the first plate ***110*** and the second plate ***120*** and facilitates pivotal or rotational movement of the first plate ***110*** and the second plate ***120***, relative to each other. With the implant ***100*** placed between vertebral bodies of a patient, the keels ***114*** and ***124*** are directed along a posterior to anterior line or in the sagittal plane of the patient. Accordingly as the patient bends forward or backward the upper plate ***110*** can pivot or rotate about the beam ***210***. When the patient bends laterally or side to side, the lower beam ***220*** can pivot or rotate in the lower channel ***160***, allowing the upper beam ***210*** to pivot or rotate about the lower beam ***220*** and also allowing the upper plate ***110*** to pivot or rotate about the lower beam ***220***,

and, thus, relative to the lower plate ***120***. In an alternative embodiment, there is a loose fit between the spacer ***130*** and the first and second plates, and, in particular, there is a loose fit between the upper beam ***210*** and the upper channel ***150*** and also between the lower beam ***220*** and the lower channel ***160***. This loose fit allows for a twisting motion about an axis that is perpendicular to the plates as, for example, perpendicular to the surface ***112*** of the upper plate. Thus, this loose fit allows for twisting about the length of the spine.

[0038] As illustrated in **FIGS. 1B, 1G** and **3**, the ridge 127 adjacent to the second surface ***126*** of the lower plate is not parallel to the first surface ***122*** of the lower plate nor to the upper plate.

[0039] The orientation of the plates ***110, 120*** in **FIGS. 1A, 1B** and **3**, show the implant ***100*** assembled in a neutral position (i.e., the position where the first plate ***110*** has not rotated relative to the second plate ***120***). The distance between the first plate ***110*** and the second plate ***120*** enable the implant to achieve movement in forward, backward, lateral and rotational directions.

[0040] **FIG. 4** shows a side view of an implant ***100*** of the invention implanted between two vertebrae ***410, 420***. Given the difference between the first plate ***110*** and the second plate ***120*** at its anterior end ***A*** and its posterior end ***P***, i.e., the distance between the plates is greater at the anterior ***A*** end than the posterior ***P*** end, forward (bending) movement is facilitated to a greater degree than backward (bending) movement. Thus, for this embodiment, an example of a forward bending movement of up to 10° can be achieved while a backward bending movement of 5° will be achieved. By sloping the lower plate and/or the upper plate toward the posterior portion, the amount of backward bending can be increased.

[0041] In a preferred embodiment, the implant can be made of titanium or a stainless steel that is approved for implantation into a patient. Other

materials that have appropriate structural strength and that are suitable for implantation into a patient can also be used.

[0042] **FIG. 6** is a block diagram showing the basic steps of the method of inserting the implant ***100*** of this invention. First the spine is exposed ***610***, then the intervertebral disk is removed ***620*** and the implant is inserted ***630***. Finally, the wound is closed ***640***. This procedure can be followed for either an anterior approach or posterior-lateral approach. Additional steps, such as cutting channels into the vertebral bodies to accept the keels of the plates and assembling the implant by inserting the crossbar member between the upper and lower plates prior to installation can also be performed without departing from the scope of the invention.

[0043] The foregoing description of embodiments of the present invention has been provided for the purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise forms disclosed. Many modifications and variations will be apparent to the practitioner skilled in the art. The embodiments were chosen and described in order to best explain the principles of the invention and its practical application, thereby enabling others skilled in the art to understand the invention and the various embodiments and with various modifications that are suited to the particular use contemplated. It is intended that the scope of the invention be defined by the following claims and its equivalence.